Kansas Medical Assistance

DRUG UTILIZATION REVIEW BOARD

Meeting Minutes, Open Session

May 12, 2004

DRUG UTILIZATION REVIEW BOARD Meeting Minutes, Open Session SRS Learning Center, Conference Rooms A & B Topeka, Kansas May 12, 2004	**Members Present:** Michael Burke, M.D., Ph.D., Chair; R. Kevin Bryant, M.D., CMD; Dennis Grauer, Ph.D.; Linda Kroeger, ARNP; John Lowdermilk, R.Ph.; Barry Sarvis, R.Ph.; Brenda Schewe, M.D.; Roger Unruh, D.O.; Kevin Waite, PharmD **SRS Staff Present:** Nialson Lee, B.S.N, M.H.A.; Mary Obley, R.Ph.; Vicki Schmidt, R.Ph., DUR Program Director; Erica Miller, Scott Brunner **EDS Staff Present:** Karen Kluczykowski, R.Ph.; Nicole Garcia, R.N.	**Representatives:** Mike Hutfles (Ks Governmental Consulting), Craig Boon, R.Ph. (Heritage Information Systems, Inc.), Chris Johnson, R.Ph. (Heritage Information Systems, Inc), Danny Ottosen (Berteck Pharmaceuticals), Mike Moratz (Merck), Barbara Belcher (Merck), Stephanie Miller (Amgen), Kathleen Carmody (Eli Lilly), Dr. Robert Calder (Merck), Dave Hanson (Pfizer), Brad Smoot (Pfizer), Brett Spencer (Purdue), Shashamk Radediya, M.D. (KUMC), Jim Baumann (Pfizer), Stephanie Cook (Boehringer Ingelheim), Hal Pierce (Healthpoint), Russell Norris (Merck), Chris Lepore (Johnson and Johnson), Bruce Hodges, M.D. (Suburban Family Physician), Jacqueline Marinac (Pfizer), Tony Ranno (Pfizer), Brian Leugs (PhRMA), Cynthia Chase (Pfizer), Nancy Zogleman (Pfizer)
TOPIC	**DISCUSSION**	**DECISION/ACTION**
I. Call to Order	• Dr. Michael Burke, Chair, called the Open Meeting of the Drug Utilization Review Board to order at 9:30a.m.	
II. Introduction of the new DUR Board Member – Roger Unruh, D.O.	• Dr. Burke introduced the new Board Member, Roger Unruh, D.O.	
III. Review and Approval of March 10, 2004, Meeting Minutes	• There were no additions or corrections to the March 2004 meeting minutes.	• A motion to approve the minutes as written was made by Dr. Schewe and seconded by

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		Dr. Bryant. The motion carried unanimously by roll call.
IV. Old Business **A. Xenical** **Discussion of Prior Authorization Criteria**	• Burke stated that the DUR Board was rather conservative the last time they reviewed this drug. The Prior Authorization required a weight loss of 5% of their pretreatment weight and Xenical and Meridia are only allowed once a lifetime. The smoking cessation drugs are allowed once a year. Should we do the same with Xenical? • Dr. Grauer reviewed the Xenical study. He stated that the study showed that the Prior Authorization process was working. 33% of the total approved for Xenical or Meridia lost 5% of their pretreatment weight. The study also looked at the cost. • Dr. Burke asked why people are being denied a Prior Authorization for a weight loss drugs. Erica stated that there are numerous reasons, for example, did not meet one of the criteria requirements, or the physician did not correctly fill out form. • Dr. Burke pointed out that the budget is not very big for this drug. Dr. Schewe stated that is because of the Prior Authorization. • Dr. Bryant requested making a change to allowing Prior Authorization once a year and then review later to see the differences. Vicki stated that we could do that, but we also have to realize that just because we don't get a renewal for the drug does not mean they failed.	
Public Comment	• No public comment.	

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Xenical - Continued DUR Board Recommendation	• With no further discussion, a motion was placed before the Board.	• A motion was made by Dr. Schewe and seconded by Mrs. Kroeger to amend the SRS recommended criteria to: One trial EACH of Orlistat (Xenical) and Subutramine (Meridia) will be allowed per beneficiary (who meets criteria) per year. The beneficiary must have lost 5% of his/her pretreatment weight within three months of initiating either drug and maintain that weight loss for continued approval of the drug. Initial requests for orlistat (Xenical) may be approved for three months if the patient meets the following criteria: 1. BMI $\geq$ 30; **OR** 2. BMI $\geq$ 27 with at least one comorbidity (diabetes, hypertension, dyslipidemia, cardiovascular disease) **AND** 3. No evidence of cholestasis. 4. No evidence of chronic intestinal malabsorption. 5. Not pregnant. 6. Not breastfeeding. 7. Treatment plan includes a nutritionally balanced, reduced- calorie diet, exercise and behavioral counseling. Renewal requests for orlistat (Xenical) may be approved for an additional three months if the patient meets the following criteria: 1. The patient has lost a total of 5% of pretreatment weight within 3 months of initiating orlistat. Initial requests for sibutramine (Meridia) may be approved for three months if the patient meets the following criteria: 1. BMI $\geq$ 30; **OR** 2. BMI $\geq$ 27 with at least one comorbidity (diabetes, hypertension, dyslipidemia, cardiovascular disease) **AND** 3.

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Xenical - Continued		Not taking a mono-amine oxidase inhibitor (MAO) (e.g. Nardil, Pamate). 4. Does not have uncontrolled hypertension. 5. Does not have unstable cardiovascular disease. 6. Does not have significant cardiac arrhythmia. 7. Not pregnant. 8. Not breastfeeding. 9. Treatment plan includes a nutritionally balanced, reduced-calorie diet, exercise and behavioral counseling. Renewal requests for sibutramine (Meridia) may be approved for an additional three months if the patient meets the following criteria: 1. The patient has lost a total of 5% of their pretreatment weight within 3 months of initiating sibutramine (regardless of whether or not they are receiving 10mg of 15mg daily). 2. Doses greater than 15mg daily will not be approved. The motion carried unanimously by roll call.
B. Expenditures for Calendar Year 2003	• Vicki stated that at the last meeting she supplied the expenditures for the year 2003 by cost. The Board requested that they would like to see the expenditures run by prescription.	
V. New Business **A. DUR 101**	• Vicki presented the DUR 101 slide presentation. • Dr. Burke pointed out that we should have included one more step on slide number 43. The final step should be, SRS makes final decision. Mary stated that she has to look at the program as a whole and occasionally the DUR Board recommendations are not instituted. • Vicki stated the Preferred Drug List (PDL) committee decides efficacy, the State looks at PDL recommendation and suggests criteria for non-preferred entities, and then the DUR Board	

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DUR 101 – Continued **Public Comment**	reviews the criteria suggested. The final decision is then made by the SRS Pharmacy Program Manager. • No public comment.	
B. Current Drugs on PA	• Vicki stated that this is a continuation of DUR 101. • The DUR Board discussed with SRS staff that the 5 Branded RX Policy is not properly working.	• SRS stated they would send out an informational newsletter regarding the 5 Branded RX Policy.
C. Vioxx – New Indication for Migraine Pain **Public Comment**	• Dr. Burke pointed out that we are reviewing Vioxx because the FDA has approved Vioxx for acute migraines • Dr. Robert Calder (Merck) stated that the FDA has recently approved Vioxx for the treatment of acute migraines. The recommended dose is 25mg, Merck does not recommend Vioxx as a treatment for chronic migraines. Dr Grauer asked if there are any studies comparing Vioxx to normal migraine medications. Dr. Calder answered that there are no studies available currently. Mr. Sarvis asked if there are any studies comparing Vioxx to NSAIDs. Dr. Calder answered that the tests were performed with Vioxx and a placebo. He also pointed out that they would like to request osteoarthritis (OA) and rheumatoid arthritis (RA) be added to the criteria. • Barbara Belcher (Merck) stated that a year ago the DUR Board reviewed Cox-2 Inhibitors and recommended that osteoarthritis (OA) and rheumatoid arthritis (RA) be approved indications for prior authorization. The DUR Board also recommended approval of prior authorization for individuals age 50 and above. SRS did not accept these and she requested that the Cox-2 Inhibitors be reviewed again for prior	

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Vioxx – Continued	authorization criteria. Dr. Burke pointed out that the agenda only has that Vioxx is being reviewed. • Bruce Hodges, M.D. (Suburban Family Physician) stated that the PA age should be 50 and above and that AO and RA should be included. In a year, around 3000 Prior Authorization requests were received for Cox-2 Inhibitors, and 61% were approved. The American Geriatric Society recommends Cox-2 Inhibitors for OA and RA. He would like to encourage the DUR Board to re-evaluate the Prior Authorization criteria. He also pointed at that the average Prior Authorization takes 8 days. Mary stated that if the physician or pharmacist does not fill out everything correctly, the process takes longer. If everything is filled out correctly it should only take a day or two. Dr. Hodges also pointed out that he is having problems with the 5 Branded RX Policy • Dr. Burke pointed out that we could review the Cox-2 Inhibitors prior authorization criteria on the next agenda (July 2004). • Shashank Radediya, M.D. (KUMC) stated that he is a Rheumatologist at the KU Medical Center. He also believes the age of the Prior Authorization should be lowered and that OA and RA should be added. He pointed out that he had a study comparing Cox-2 Inhibitors and NSAID efficacy. Mary asked if we would be able to get a copy of that study. Dr. Radadiya said he would send the State a copy. • Dr. Burke pointed out that we do need to revisit the Cox-2 Inhibitors Prior Authorization. It needs	

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Vioxx – Con't	to be placed on the next DUR meeting as a formal item and that should give the State time to pull additional data. Vicki stated that she would get some statistics put together for Cox-2 Inhibitors. Vicki also wanted to point out that ifOA, RA, and the age are changed, that there will still be a Prior Authorization process. We don't have an automatic Prior Authorization process like Missouri. • Dr. Burke also requested information comparing Kansas and Missouri Medicaid. • Barbara Belcher (Merck) asked if the DUR Board was going to wait to look at the whole Prior Authorization form until the next meeting or are they going to look at the migraine portion today. Dr Burke stated that he thinks they should at least finish the migraine portion of the Prior Authorization. • Mary pointed out that we might want to add acute migraines to the form. Dr. Schewe asked if we should place a number limit on Vioxx like we do for Triptans. Mary stated that we could make it part of the Prior Authorization criteria. Dr. Grauer stated that it should be acute treatment of migraine. Dr. Schewe thinks that this could be abused, so we should place limits on Vioxx for migraines. Dr. Calder (Merck) stated that he would not recommend more than 5 a month. The Board discussed making the Prior Authorizations last for one or 2 months at a time. Dr. Schewe suggested that we add acute treatment of migraines to the Prior Authorization and then look at Vioxx again in 3 months. Mr. Sarvis stated that he thinks we should review data in 6 months to a year. Vicki stated that we	• The prior authorization criteria for the Cox-2 Inhibitors will be an agenda item for the July 14, 2004 meeting. • Information will be available comparing Kansas to Missouri regarding the PA criteria.

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Vioxx – Continued **DUR Board Recommendation**	could review in 3 months and then again in 6 months. • With no further discussion, a motion was placed before the Board.	• A motion was made by Dr. Schewe and seconded by Dr. Unruh to amend the SRS recommended criteria to: Must meet one of the following: • Consumer age is > or = to age 65 on Date of Service. (Approve PA if system edits not forcing claim.) • Consumer under the age of 65 with one or more of the following: 1. A written statement from the prescribing physician documenting a history of GI irritation. 2. A written statement from the prescribing physician documenting a history of GI Bleed. (Including, but not limited to the following diagnosis.) 578.0-Hematemesis, 578.9-Hemorrhage of Gastrointestinal Tract 3. A written statement from the prescribing physician documenting a history of NSAID-induced ulcer (Including, but not limited to the following diagnosis.) 569.82-Ulceration of Intestine, 569.85-Andiodysplasia of Intestine with Hemorrhage, 569.86-Dieufafoy Lesion (Hemorrhagic) of Intestine 4. Consumer taking concomitant oral corticosteroid therapy within previous 31 days (i.e. Prednisone) 5. Consumer taking concomitant anticoagulant therapy, within previous 31 days (i.e. Warfarin). • Consumer has a diagnosis of familial adenomatous polposis (FAP) **Celebrex Only**

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Vioxx – Con't		• Acute treatment of a migraine **Vioxx Only** • Consumer at high risk for colorectal cancer. (High Risk defined as: 80-100% lifetime risk of developing colorectal cancer due to a germline mutation with genetic predisposition. (Hawk, DuBois, 2001:37th Annual Meeting of the America Society of clinical Oncology.) • SRS will review usage of Vioxx in 3 months and 6 months. The motion carried unanimously by roll call.
D. DUR Newsletter Topics Since 2000 **Public Comment**	• Vicki stated that this is informational only. Dr. Schewe pointed out that the in the past newsletters had several different articles and lately the newsletters have only had one topic. Will it always be this way? Craig answered that the past few topics have been rather large, the next newsletters should have more information. • No public comment.	
E. Discussion of 3rd Quarter Intervention – Pediatric Use of Antidepressants	• Chris Johnson, R.Ph (Heritage Information Systems) presented a slide presentation regarding pediatric use of antidepressants.	• The DUR Board requested a copy of the intervention letter that will be sent.
F. Additional Public Comment Before Adjournment	• Nancy Zogleman (Pfizer) stated that she did not receive the revised agenda until Monday. The short timeline left no time for preparation. The thought was that all Cox- Inhibitors would be discussed.	
VI. Meeting Adjournment	• There being no further discussion, a motion to adjourn was placed before the Board.	• A motion was made by Dr. Schewe and seconded by Dr. Unruh to adjourn the meeting. The motion carried unanimously by roll call. The open meeting was adjourned at 11:50 a.m.